

REMARKS

Status of The Claims

Claims 1-6, 10, 13, 27, and 33-35 are currently pending.

Claims 1, 2, 10, 34, and 35 are currently amended.

Claim 36 is new. Support for this claim is at page 11 of the specification, lines 7-17.

Response To Claim Objections

Claim 1 is objected to because it does not begin with the article “a.” In response, Applicants amend claim 1 to read “A seed”

Claim 2 is objected to because it does not start with the article “an.” In response, Applicants amend claim 2 to read “An alfalfa plant”

Response Regarding Rejection Of Claim 10 (35 U.S.C. § 112, ¶ 2)

The Examiner rejects claim 10 under the second paragraph of 35 U.S.C. § 112 as being indefinite because the limitation “alfalfa event J-101” is an arbitrary term unless defined by its ATCC accession number. In response, Applicants amend claim 10 to state that the alfalfa event J-101 is an event, a representative seed of which is deposited as ATCC accession no. PTA-4814.

Response Regarding Rejection Of Claims 1-6, 10, And 35 (35 U.S.C. § 112, ¶ 1)

The Examiner rejects claims 1-6, 10, and 35 under the first paragraph of 35 U.S.C. § 112 as failing to comply with the enablement requirement because the “specification does not disclose a repeatable process to obtain the plant and it is not apparent if the plant is readily available to the public.” In response, Applicants submit herewith a declaration stating that a

deposit was made under the terms of the Budapest Treaty and that the instant invention will be released to the public irrevocably and without restriction upon the issuance of a patent.

Response Regarding Rejection Of Claims 13, 27, 33, And 34 (35 U.S.C. § 112, ¶ 1)

The Examiner rejects claims 13, 27, 33, and 34 under the first paragraph of 35 U.S.C. § 112 because, while being enabling for alfalfa plant J-101 representative seed deposited with ATCC with Accession No. PTA-4814 and progeny produced therefrom comprising event J-101, the specification does not reasonably provide enablement for any glyphosate tolerant alfalfa plant comprising SEQ ID NO:1 or SEQ ID NO:2.

In response, Applicants submit that the claimed invention can be easily practiced by skilled artisans with little or no experimentation. For example, all that is required is the acquisition of seeds containing the pMON20998 genetic event from a descendent plant or from the ATCC, where sample seeds are deposited under accession number PTA-4814. Determining whether or not seeds from a descendent plant carry the event is a matter of performing any number of well-known sequence analyses. These analyses would minimally entail determining whether plants grown from the seeds comprise SEQ ID NO:1 or SEQ ID NO:2. Once these junction sequences are identified, further analysis could include testing for the presence of the EPSPS, CP4, (*see* Figure 7, which clearly shows that the EPSPS encoding sequence is the CP4 gene) encoding sequences between the junctions. Given the availability of the claimed subject matter and the ease of detection thereof, there is no reason for skilled artisans to attempt producing the claimed alfalfa plant *de novo*, neither would skilled artisans be inclined to do so.

In view of the above amendments and remarks, Applicants respectfully submit that the pending claims are completely enabled.

Response Regarding Rejection Of Claims 4-6, 13, 27, And 33-35 (35 U.S.C. § 112, ¶ 1)

The Examiner rejects claims 4-6, 13, 27, and 33-35 under the first paragraph of 35 U.S.C. § 112 as failing to comply with the written description requirement. The Examiner's rejection provides that the specification does not describe other glyphosate tolerant alfalfa plants comprising SEQ ID NO:1 and SEQ ID NO:2 or SEQ ID NO:3 and SEQ ID NO:4 besides that characterized by J-101 genetic event.

Claims 4-6, 13, 27, and 33-35 find written description in the original application through its disclosure of a particular isolate (event J-101) which embodies a glyphosate tolerant alfalfa plant as recited by these claims. This isolate contains the genetic locus comprising the insertion of pMON20998 (illustrated in Figure 1); the 5' and 3' junctions of this DNA insert with the alfalfa genomic sequence are minimally comprised of SEQ ID NO:1 and SEQ ID NO:2, respectively (*see* Example 2). Regarding written description and enablement, skilled artisans would readily understand that this locus can be predictably transferred from one genetic background to another by means of breeding or crossing. Indeed, the instant specification reviews this point when it states that the "invention provides a glyphosate tolerant alfalfa plant that has all of the physiological and morphological characteristics of the alfalfa event J-101 of claim 1 and the progeny plants and parts thereof" (*see* page 4, paragraph 1) and discloses that the locus can be inherited (*see* specification at page 10, line 19, though page 12, line 8). Certain progeny from such a cross would carry the locus in a genetic background different from each parent and would constitute other examples of alfalfa plants that embody the claim recitations. In view of the above argument, Applicants respectfully request the withdrawal of the rejection of claims 4-6, 13, 27, and 33-35 as lacking written description.

Response Regarding Rejection Of Claims 4-6, 10, 13, 27, And 33-35 (35 U.S.C. § 103(a))

The Examiner rejects claims 4-6, 10, 13, 27, and 33-35 under 35 U.S.C. § 103(a) as being obvious over Fincher *et al.* (U.S. Pat. No. 6,462, 258 B, issued October 8, 2002). The Examiner states that Fincher *et al.* teaches pMON20988 and teaches that “alfalfa is a suitable target plant of interest for the nucleic acid constructs of the invention.”

Claims 4-6, 10, 13, 27, and 33-35 pertain to an alfalfa plant of event J-101. By definition, this event is glyphosate tolerant and comprises an EPSPS encoding sequence and a specific integration site for the transgene construct within the alfalfa genome that is defined by the junction sequences SEQ ID NOS:1-4; *i.e.*, the integration of the transgene is at a location specifically defined by the sequences SEQ ID NOS:1-4 which represent the junctions between the DNA insert and alfalfa DNA. This event is **NOT** obvious and could not have been predicted by Fincher *et al.*

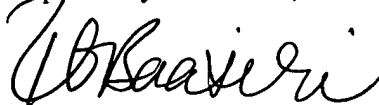
Fincher *et al.* does not suggest the use of EPSPS expression vectors *at this genomic site* in order to derive glyphosate tolerant alfalfa plants. When alfalfa plants are transformed with pMON20988, the multitude of resulting events do not necessarily express the gene at levels that render the transformed plant glyphosate tolerant. The integration at a specific site is what makes the event J-101 of superior characteristics. The integration site is not predictable and could not have been predictable from the disclosure of pMON20988 and the suggestion to transform alfalfa by Fincher *et al.* Claims 4-6, 13, 27, 33, 34, and 35 pertain to event J-101. The alfalfa plants of said claims have the same scope as claims 1 and 2 but are worded differently. Any alfalfa event that is glyphosate tolerant has an EPSPS encoding sequence, and the junction sequence SEQ ID NOS:1-4 is a J-101 event regardless of the genetic makeup of this event. One

representative of this event is deposited as ATCC deposit PTA-4814. The originally produced plant and its transgenic descendents constitute the only reasonably possible examples that can embody the claimed plant.

Fees

A request for a two-month extension of time and the authorization for the associated fee are filed concurrently with this paper. Should any additional fees under 37 C.F.R. §§ 1.16-1.21 be required for any reason relating to the enclosed materials, the Commissioner is hereby authorized to deduct any additional fees from Howrey LLP Deposit Account 08-3038/11899.0237.PCUS00.

Respectfully submitted,



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